METHOD AND APPARATUS FOR RAPID DEPLOYMENT CHEST DRAINAGE

This application claims priority benefit under 35 USC § 119(e) from U.S. Provisional Application No. 60/447,110 filed June 9, 2003, and U.S. Provisional Application No. 60/415,188 filed September 30, 2002.

Field of the Inventions

The inventions described below relate the fields of general surgery, cardiothoracic surgery, trauma surgery, combat medicine, and emergency medical services.

Background of the Inventions

Chest drainage tubes are flexible tubes that are placed into a patient's chest cavity to allow for drainage of fluids following trauma or surgery. These chest tubes have one or more holes at the distal end through which the fluid is evacuated from the chest cavity into the lumen of the chest tube. The proximal end of the chest tube includes connectors to allow for passage of the drained fluids from the lumen of the chest tube into a collection device or apparatus. The chest tubes or collection apparatus typically include features to prevent backflow of air into the chest cavity, thus preventing pneumothorax. These backflow prevention features include shutoff valves and duckbill valves. Typical collection apparatus comprises gravity fed drains or vacuum or pump powered drainage mechanisms.

Chest tubes are typically placed into a patient with a stiff trocar mounted to the internal lumen. The trocar

is stiff, relatively pointed at the distal end, and allows for advancement of the flexible chest drainage tube into an incision in the chest wall. The stiff, pointed trocar is useful for initial insertion of the chest tube but becomes a dangerous instrument once the chest tube is advanced below the level of the ribs. Use of such internal trocars is not appropriate for non-physician insertion because of the inherent danger of heart or lung perforation.

Maintenance of sterility has always been problematic with chest tubes. Placement of a chest tube, especially in the emergency setting, requires sterile scrub of the incision area and incision into the chest wall with sterile instruments. These incisions are, understandably, difficult to perform aseptically in the field, where the insertion site may be bloody, dirty or otherwise contaminated. In addition, maintenance of sterility in the area of chest tube penetration into the chest has been difficult as has been the ability to hold the chest tube in position once it has been introduced into the patient. The use of surgical gloves to maintain sterility becomes problematic since the gloves become contaminated quickly in the typical field environment.

New devices and methods are needed to permit rapid placement of chest tubes by less trained individuals in contaminated environments. In addition, improved devices and methods of maintaining sterility at the chest tube wound site and holding the chest tube in place are needed.

Summary of the Invention

This devices and methods described herein provide for placement of chest tubes in contaminated environments using

rapid deployment techniques, for maintaining sterility at the penetration site on the patient's chest where the chest tube emerges, and for improved methods of holding the chest tube in place. The present invention is a chest tube that is provided with a double aseptic package that maintains sterility and cleanliness of the chest tube in contaminated environments. The chest tube includes a cannula with a sharpened distal end and a blunt trocar or nose cone that selectively shields or exposes the sharpened distal end.

In another embodiment, a region on the chest tube is configured to allow for maximum friction while gripping the chest tube through the package material. In another embodiment, a region on the packaging is fabricated from gripping material to facilitate pushing the chest tube inside the packaging. The region on the packaging optimized for gripping the chest tube is optionally fabricated from elastomeric material to facilitate moving the chest tube inside and relative to the inelastic package. In another embodiment, the blunt trocar itself is shaped so as to penetrate the package without the need of a separate sharp tip. This blunt trocar is also suitable for blunt dissection into the chest wall once the initial incision has been completed.

The chest tube may further include a malleable region along part or all of its length to facilitate bending of the chest tube into a pre-determined shape. The use of a curved or bent shape on the part of the chest tube facilitates placement beneath the ribs but above the lungs and heart.

Another feature of the invention is a patch, disc, plate or membrane of adhesive-faced impermeable material

that is adhered to the site where the wound will be created in the chest wall. The patch may also be coated with materials that have disinfectant properties. The patch also includes straps disposed, for example, in a starburst pattern. Once the site has been swabbed with disinfectant, the disc of material is adhesively placed on the skin at the site of the incision. The incision is now made through the patch of material. This patch serves as a sterile barrier following placement of the chest tube. The straps serve to hold onto the chest tube to maintain its position once placed. The straps are wrapped around the chest tube and adhesively affixed to the shaft of the chest tube after placement, thus securely holding the chest tube to the disc, which is affixed to the chest wall of the patient. The patch is optionally pre-mounted to the chest tube inside the package. In this embodiment, the chest incision is performed prior to attachment of the patch to the patient. In another embodiment, the disc is integral to the inner packaging material so that once the outer packaging material is removed, the patch may be immediately placed against the chest over the region of the incision.

In another embodiment of the invention, a chest tube is designed with an integral tip that permits the chest tube to be advanced out of the package by forcing a fenestration in the package wall or seal. The integral tip may be a cutting member that is selectively exposed by the operator and then retracted following package penetration. This same cutting member may also be used to make the initial incision in the chest wall of the patient. The member that re-protects the cutting edge may be a blunt nose that is suitable for bluntly dissecting the tissue between the ribs. In another embodiment of the invention,

the blunt nose is configured to form a wedge so that it is able, itself, to force a fenestration in the package or package seal, thus obviating the cutting edge.

The chest tube package may be configured with a region that allows for manipulation of the contents so that the chest tube may be advanced out of the package by manual application of force. The region permitting manipulation is an elastic area that is deformable relative to the rest of the package or it is a movable region with a sliding seal between itself and the rest of the package. Either method maintains sterility within the package during moving of the contents. The inner package containing the chest tube may also comprise a region that is specially designed to facilitate penetration by the chest tube. This penetration region is a weakened part of the heat seal or a specially designed port that opens only to permit the chest tube to penetrate the inner package.

To facilitate placement of the chest tube, a specialized cutter is configured to perform the initial incision into the chest wall without penetrating below the level of the ribs. This specialized cutter comprises safety features to prevent premature deployment and to prevent cutting too deeply into the chest. This cutter is actuated by manual, electrical or hydraulic/pneumatic force. It may be configured to be a positive displacement cutter or it may be a punch that is loaded and fired or activated under pre-determined force.

The chest tube comprises a short insertion portion (the distal segment intended and adapted for insertion into the body of the patient) and a stop to prevent it from being inserted too far into the patient. The short

insertion portion has a blunt distal end and is capable of being inserted into a fenestration or incision in the chest wall that was created by either a scalpel and blunt dissection as would be performed by a gloved finger, a Kelly clamp, or a specialized trocar and obturator. The short chest tube is inserted through the incision into the chest cavity. The short chest tube projects through the skin, fat, fascia, between the ribs, and finally through the pleural lining. The tip of the chest tube is soft or blunt or both, and contains no edges or roughness that might erode underlying tissues. The short chest tube is terminated on its proximal segment (proximal to the stop) with a manually openable and closeable valve or it is terminated with a one-way valve that permits only removal of fluids and air from the chest cavity. The short chest tube comprises a flange that prevents excessive penetration into the chest cavity. The flange is designed to stop at the level of the skin surface, or, in another embodiment, the flange is smaller and is inserted into the incision but does not penetrate below the level of the top of the ribs.

In yet another embodiment, should lateral penetration of the chest tube be desirable, the short chest tube comprises a trocar and obturator that bluntly penetrates the incision to a pre-determined depth such that it is depth-limited. The trocar further comprises a right angle turn at its distal end that serves to deflect a secondary longer chest tube that is placed through the trocar and which extends laterally in the pleural space to the desired location. The trocar and secondary chest tube comprise a seal system to prevent gas passage between the two components. The trocar further comprises an angular orientation marker that provides an indication to the

operator of the direction where the secondary chest tube will be deflected. The orientation markers may be aligned by the practitioner to point to the head or the feet (or other anatomical landmark) so that the deflection is always in a pre-determined direction.

The short chest tube may be installed on a patient by unskilled or relatively unskilled medical personnel to treat a trauma pneumothorax in the field. It cannot be placed unsafely and thus paramedics or Emergency Medical Technicians (EMTs) may install the chest tube into patients while they are in the field or the emergency department. The short chest tube is preferably coupled with a specialized blunt or automatic tissue dissector that safely dissects an incision through the ribs.

Brief Description of the Drawings

Figure 1A illustrates a side view of a chest tube.

Figure 1B illustrates a lateral cross-section of the central area of the chest tube comprising a generally circular cross-sectional profile.

Figure 1C illustrates a lateral cross-section of the central area of the chest tube comprising a generally elliptical cross-sectional profile.

Figure 2A illustrates a side view of the distal tip of the chest tube with a blunt trocar or obturator in the advanced configuration so that the sharp cutter edge of the trocar is protected.

Figure 2B illustrates a side view of the tip of the chest tube with the blunt trocar or obturator in the

retracted configuration so that the sharp edge of the cutter is exposed.

Figure 2C illustrates a side view of the tip of the chest tube with the blunt trocar or obturator and the cutting blade retracted and removed back through the proximal end of the chest tube.

Figure 3A illustrates a double aseptic package around the chest tube.

Figure 3B illustrates the aseptic package with the outer layer removed.

Figure 3C illustrates the aseptic package with the chest tube advanced out through the inner layer of the package.

Figure 4 illustrates the chest tube advanced into a wound in the thoracic wall of a patient or other animal.

Figure 5A illustrates a top view of a protective wound disc.

Figure 5B illustrates a top view of the protective wound disc with its straps wrapped around and adherent to the chest tube.

Figure 6A illustrates a side view of a chest wall punch, with a retracted blade.

Figure 6B illustrates a side view of a chest wall punch with the blade advanced.

Figure 6C illustrates a bottom view of a chest wall punch with the blade advanced.

Figure 7 illustrates a side view of a chest tube, comprising a blunt trocar suitable for penetrating the package and bluntly dissecting into the chest of the patient.

Figure 8A illustrates a top view of a chest tube in a package comprising an integral protective wound disc and tie down straps.

Figure 8B illustrates a top view of a chest tube in a package comprising an integral protective wound disc and tie down straps along with an integral pleural drainage system.

Figure 9A illustrates a side view of an expandable sheath and blunt obturator.

Figure 9B illustrates a bottom view of the expandable sheath and blunt obturator.

Figure 9C illustrates a side view of the expandable sheath with the blunt obturator removed and a tapered expanding obturator just being inserted.

Figure 9D illustrates a side view of the expandable sheath with the tapered expanding obturator fully inserted so that the collet-like split sheath sides are fully expanded.

Figure 9E illustrates a bottom view of the expandable sheath with the tapered expanding obturator fully inserted.

Figure 10A illustrates a side view of a short chest tube, shown placed through a cross-sectional view of the outer chest wall.

Figure 10B illustrates a side view of a short deflecting trocar and chest tube placed into a thorax or chest wall of a patient.

Detailed Description of the Invention

Figure 1A illustrates a side view of a chest tube **10** of the present invention. The chest tube **10** comprises a length of cannula tubing **12**, an optional integral valve **13**, a plurality of drainage ports **14**, an optional region of gripping surface **15** on the cannula tubing **12**, a drainage lumen **16**, a drainage connector **18**, a cutter **20**, a cutter handle **22**, an obturator **24**, an obturator handle **26** a cutter control mechanism **28**, an obturator control rod **30** (see Figures 1B and 1C), and a malleable shaft **32**. The cannula tubing **12** is an axially elongate hollow tube affixed at the proximal end to a drainage connector **18**. The central or through lumen of the drainage connector **18** is in communication with the lumen **16** of the chest tube **10**. The drainage ports **14** are penetrations communicating from the outside of the cannula tubing **12** and are in communication with the inner lumen **16**. The cutter **20** is affixed to the distal end of the cutter control mechanism **28**. The cutter control mechanism **28** is slideably affixed within the central or drainage lumen **16** of the cannula tubing **12**. The cutter handle **22** is affixed to the proximal end of the cutter control mechanism. The obturator **24** is affixed to the distal end of the obturator control rod **30**, which is slideably mounted within the drainage lumen **16** of the cannula tubing **12**. The obturator handle **26** is affixed to the proximal end of the obturator control rod **30**. The malleable shaft **32** is affixed to or integral to the cannula tubing **12** and runs along at least a portion of the length

of the cannula tubing **12**. The obturator control rod **30** and the cutter control mechanism **28** both traverse the cannula tubing **12** from approximately its proximal end to approximately its distal end. The valve **13** is optional and is optionally configured integrally to the cannula tubing **12** or removably affixed to the drainage connector **18**. The gripping surface **15** is integral to the cannula tubing **12** or it is optionally a separate structure that is movably able to grip the cannula tubing **12**.

Further referring to Figure 1A, the chest tube **10** is designed to be placed within a patient's chest and into the patient's chest through an incision in the patient's chest to provide for drainage. Using additional components such as a stopcock or one-way valve **13**, the chest tube prevents backflow of air or contaminants back into the chest. Such backflow of air or contaminants could lead to a pneumothorax or infection.

The valve **13** comprises a closeable central orifice that is also openable permitting the obturator control rod **30**, the cutter control mechanism **28**, the cutter **20** and the obturator **24** to pass therethrough. The valve **13** is either a one-way valve permitting flow only from the distal tip of the chest tube **10** and not retrograde back toward the distal tip of the chest tube **10** (a duckbill valve, for example) or a stopcock type valve (a ball valve). The valve **13** may be integral to the chest tube **10** or a separate component added proximal to the drainage connector **18**.

The gripping surface **15** may be a region of roughness on the surface of the cannula tubing **12**. This roughness may be created by a series of protrusions or depressions in the surface of the cannula tubing **12**, or any other

texturing or knurling. The gripping surface **15** may also be a separate structure that is slidably, concentrically affixed to the cannula tubing. When the gripping surface **15** is withdrawn proximally, it slides relative to the cannula tubing **12**. When the gripping surface **15** is advanced distally, it grips the cannula tubing **12** in the same manner as a jamb cleat and advances the cannula tubing **12** distally.

The materials used in the manufacture of the cannula tubing **12** of the chest tube **10** include but are not limited to polyvinyl chloride, PEBAX, polyurethane, polyester, polyethylene, PEEK, polypropylene, polytetrafluoroethylene, polyetheretherketone, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoromethylvinylether and silicone rubber. In order to minimize the risk of kinking, the wall of the cannula tubing **12** may be extruded with integral spiral or braided reinforcements manufactured from materials such as but not limited to stainless steel wire, polyimide strands and the like. The cannula tubing **12** may be manufactured from materials with variable durometer or hardness. For example, the proximal end of the cannula tubing may be of harder durometer or thicker wall construction to make that area stiffer than the distal end, thus enhancing pushability and column strength of the chest tube **10**.

The obturator control rod **30** and the cutter control mechanism **28** possess column strength and are inelastic in tension. The obturator control rod **30** and the cutter control mechanism **28** are, however flexible to at least some degree and allow bending of the chest tube **10** to minimize the risk of perforating internal organs on the patient

while the chest tube **10** is being inserted. The obturator control rod **30** and the cutter control mechanism **28** are fabricated from materials such as, but not limited to, stainless steel, nitinol, Elgiloy and the like. The structures of the obturator control rod **30** and the cutter control mechanism **28** are a solid or tubular axially elongate metal or, preferably, a coil or double helix or a braided reinforcement with a polymer coating or co-extrusion. Such polymer coatings include, but are not limited to, Pebax, PVC, PEEK, PTFE, PET, PETG, polyethylene, polypropylene and the like.

The interior walls of the tube **12**, which form the exterior of the drainage lumen **16** and the distal ports are optionally coated with anti-thrombogenic materials to minimize the risk of thrombus. The anti-thrombogenic materials include but are not limited to heparin. The anti-thrombogenic materials are mechanically, covalently or ionically bonded to the material of the tube **12**. The valve **13** and the inner lumen of the drainage connector **18** may also be coated with similar anti-thrombogenic agents. The exterior of the tube **12** as well as the interior surfaces of the chest tube **10** are optionally coated with antibiotics to minimize the risk of infection. This is especially important in contaminated environments. Such antibiotics include but are not limited to erythromycin, amoxicillin, sulfa drugs and the like.

The diameter of the cannula tubing **12** ranges from 1mm to 30mm and preferably between 2mm and 15mm. The length of the cannula tubing **12** ranges between 10cm and 200cm and most preferably ranges between 30cm and 100cm.

The malleable shaft **32** is preferably a length of stainless steel or other metal that is embedded within the wall of the cannula tubing **12**. This malleable shaft may or may not be removable from the chest tube **10**. The malleable shaft **32** extends along at least a portion of the cannula tubing **12** but preferably extends along the full length of the cannula tubing **12**. The malleable shaft **32** is sized so that it may be bent by manual force but resists bending by resilient or elastic forces imposed thereon by the cannula tubing **12**.

The drainage connector **18** is preferably fabricated from materials such as but not limited to polycarbonate, polyvinyl chloride, polyethylene, polypropylene and the like. The drainage connector **18** is preferably insert molded or affixed using adhesives to the cannula tubing **12**. The drainage connector **18** preferably comprises a single through lumen. The drainage connector **18** may, however, be "Y" shaped or trident shaped and have multiple connections. Such connections typically use hose barb type fittings but may also have Luer type fittings or other bayonet or threaded connections for interface with other equipment. The drainage connector **18** is sized so that the cutter control mechanism **28** and the obturator control rod **30** may be slideably passed therethrough. The drainage connector **18**, preferably is sized so that the cutter **20** and obturator **24** may be completely removed from the chest tube **10**.

The cutter **20** is preferably a circular cutter with its edge beveled to the outside. A circular cutter is also known as a trephine. The plane of the front edge of the circular cutter **20** is preferably not orthogonal to the axis of the tube **12** of the chest tube **10**. The plane of the

front edge of the circular cutter **20** is, preferably, disposed at an angle between 5 degrees and 60 degrees from the plane that is orthogonal to the axis of the chest tube **10**.

Figure 1B illustrates a lateral cross-section of the central area of the chest tube **10** with the cannula tubing **12** cross-section showing the malleable shaft **32** as an integral part of the tubing. The drainage lumen **16** of cannula tubing **12** has the cutter control mechanism **28** and obturator control rod **30** running co-axially throughout the length of said lumen **16**. The cross-sectional outer profile of the cannula tubing **12** is generally circular.

Figure 1C illustrates a lateral cross-section of the central area of another embodiment of the chest tube **10** with the cannula tubing **12** cross-section showing the malleable shaft **32** as an integral part of the tubing. The drainage lumen **16** of the cannula tubing **12** further comprises the cutter control mechanism **28** and the obturator control rod **30** running coaxially throughout the length of said lumen **16**. The outer profile of the cannula tubing **12** is generally elliptical. An elliptical or rounded rectangular cross-sectional configuration enhances placement of the chest-tube through the intercostal space. By aligning the major axis of the ellipse with the direction of the rib disposition and the minor axis transverse to the direction of the ribs, a chest tube of larger drainage capacity than would normally be allowed by the rib spacing may be inserted between the ribs. Clamps and other devices can be used to insert a large round chest tube that would not normally fit between the ribs except by compressing, or pre-flattening, the tubing cross-section

prior to insertion. This compression technique is tedious, wastes time, requires sterile equipment and technique, and increases the chance of contamination to the patient.

Figure 2A illustrates a side view of the distal end of the cannula tubing **12** comprising the cutter **20** and obturator **24**, further comprising the plurality of drainage ports **14**. The cutter **20** and obturator **24** are in the extended or protected position.

Referring to Figure 2A and 1A, the cutter **20** is blunted or protected by the extended obturator **24** so that the sharp edge or sharp tip of the cutter **20** cannot inadvertently cut through the sterile packaging of the chest tube **10**. Such blunting or protection of the cutter **20** by the obturator or blunt tip **24** is selective or controllable. The cutter control mechanism and obturator control rod thus provide means for longitudinally translating the cutter relative to the obturator, so that it may be selectively extended to put the cutting edge distal of the obturator. The means for longitudinally translating the cutter may also be implemented such that the obturator is longitudinally fixed relative to the cannula tubing, in addition to the longitudinally slidable obturator illustrated in the figures..

Figure 2B illustrates a side view of the distal end of the cannula tubing **12** comprising the cutter **20** and obturator **24**, further comprising the plurality of drainage ports **14**. The cutter **20** is in the extended position while the obturator **24** slightly retracted.

Referring to Figure 2B, the obturator **22** is slightly retracted to expose the sharp edge of the cutter **20**. The

sharp edge of the cutter **20** is now useable to punch through the packaging of the chest tube to facilitate using the tube in emergency conditions or contaminated environments.

Figure 2C illustrates a side view of the distal end of the cannula tubing **12** comprising the plurality of drainage ports **14**. Referring to Figures 1A and 2C, the cutter **20** and obturator **24** are not visible in this view, as they have been removed from the cannula tubing **12** to open the drainage lumen **16** in order to perform the designed function of the chest tube **10**.

Figure 3A illustrates the packaging **40** of the present invention. The packaging **40** contains the chest tube **10**, and comprises an outer package **42** and an inner package **44**. The outer package **42** and inner package **44** are sterile barriers for the chest tube **10**. The inner package **44** and the outer package **42** are, preferably, polyethylene pouches that are closed using heat seals. The heat seals are typically from 1/8 inch to 1/2 inch wide around the perimeter of the pouches. The pouches may have regions fabricated from sterile barrier such as Tyvek that is suitable for use with ethylene oxide (ETO) sterilization and allows said ETO to pass into the pouch but prevents contamination from entering the pouch. The weakened area of the seal can be an area where the seal is less wide (1/8 to 1/16 inch) than the rest of the seal.

In another embodiment, the outer package **42** is a tray fabricated from materials such as but not limited to polystyrene, polyvinyl chloride, PETG and the like. The trays are typically thermoformed and are covered with a lid fabricated from Tyvek, PETG, polyethylene or the like. The lid is preferably heat sealed to a flange at the open end

of the tray. A tray is advantageous over a pouch in that it offers protection against crushing that is not provided by the pouch. The tray, however, is larger, heavier, and more difficult to store and dispose.

The double sterile barrier is intended to give the practitioner the option of not using the device after initial assessment of the patient and also for cleanliness and sterility purposes in the field.

Figure 3B illustrates the packaging **40** with the outer package **42** removed. The inner package **44**, further comprising a gripping region **48**, is still sealed and protects the chest tube **10** from contamination. The gripping region **48** provides an area on the package where the operator may more easily grab the chest tube **10** without slipping. This gripping region **48** is a high friction region relative to the rest of the package. The gripping region **48** is, in a further embodiment, elastomeric in structure and allows the operator to advance the chest tube **10** while the flexible or inflexible, but inelastic, inner package **44** remains relatively undistorted and stable. Suitable materials for fabricating the gripping region **48** include, but are not limited to, polyurethane, silicone rubber, thermoplastic elastomers such as C-Flex, and latex rubber.

In yet another embodiment, the gripping region **48** is movably attached to the inner package **44** by means of a sliding or moving seal. This sliding or moving seal is a gasket between the gripping region **48** and the inner package **44** that prohibits passage of contaminants into the inner package **44** but still permits translation or movement of the gripping region **48** relative to the inner package **44**. In

one exemplary embodiment, the gripping region **48** includes a plunger that impinges on the friction surface 15 on the chest tube **10**. The operator depresses the plunger or gripping region **48** and the chest tube **10** is forced against and through the inner package **44** seal at seal penetration point **46**.

Figure 3C illustrates the packaging **40** of the chest tube **10** in the inner package **44**, further comprising the gripping region **48**, with the obturator handle **26** in the partially retracted position. The chest tube **10** in this configuration will allow inner package seal penetration **46** to occur as a result of advancement of the chest tube **10** with the cutter **20** exposed, thus penetrating the inner package **44** seal. The obturator **24** is not visible in this view as it is retracted into the cutter **20** and cannula tubing **12**. This allows for cutter **20** penetration through the inner package **44** at the seal penetration point **46** to maintain sterility until advancement and deployment into the patient.

In another embodiment of the invention, the inner package **44** seal is weakened at a specific area where the chest tube is intended to penetrate the seal. This weakened area is, preferably, visibly marked with indicia adequate to inform the practitioner of the location of the weakened area (and, thus, the preferred point of exit) to ensure that the chest tube penetrates the seal at the weakened area of the inner package **44**. In yet another embodiment, an openable window is provided in the inner package **44** where the chest tube is to be advanced out of said inner package **44**. This openable window is, for example, a normally closed elastomeric valve (a duckbill or

slit membrane) that is pried open by the chest tube obturator or its cutter. An optional thin seal layer is used to maintain sterility over the openable window, prior to opening.

Figure 4 illustrates the method of installing the device **50** into a patient. The chest tube **10** is contained in a sterile inner package **44** until ready for deployment into patient **52** through an incision site **54**. The access site is first prepared by swabbing or rinsing the area with betadine or other disinfectant, preferably using standard hospital or emergency procedures. The adhesive patch described below or other flexible structure further comprising a disinfectant is applied to the region of the incision. An incision is made in the chest wall using a sterile scalpel, punch or other device. A finger or, alternatively, other blunt device is next advanced through the incision to bluntly dissect through the final layers of chest wall into the chest cavity. The blunt device for dissection may optionally be comprised at the distal tip of the chest tube itself. To deploy the chest tube from its protective package, the user first opens and removes the outer sterile or aseptic packaging layer, maintaining the inner package substantially intact, so that the chest tube can be placed without the need for sterile gloves to be worn by the user. Next, the user grasps the chest tube and the blunt trocar control knob through the inner layer of flexible packaging. The blunt trocar is manually retracted within the cannula exposing the sharpened distal tip of the cannula. The cannula is punched through the inner layer of package by way of the sharp tip and the blunt trocar is now replaced to its protective position. The chest tube is now advanced into the prepared incision in the chest cavity.

During deployment, the inner package is left intact over the chest tube, while only the distal end of the tube extends out of the package, ensuring sterility of the chest tube to the maximum extent possible.

Figure 5A illustrates an aseptic hold-down patch **60** to be used with the chest tube. The aseptic hold down patch **60** comprises a penetration region **62**, a main adhesive region **64**, a hold down plate **66**, a plurality of hold down straps **68**, an adhesive region **70** on each strap, a plurality of pull tabs **72**, and a plurality of partially completed slits **74** within the penetration region **62**. As illustrated, the patch is a disc, but it may be provided in any suitable shape.

Referring to Figure 5A, the main adhesive disc **64** is permanently affixed to the hold-down disc **66** with adhesive or other fasteners. The hold down-straps **68** are affixed to or integral to the hold-down disc **66**. The adhesive region **70** is on the hold-down strap **68** and the pull-tab **72** is at the end of the hold-down strap **68**. The penetration region **62** is at the center of both the main adhesive disc **64** and the hold down disc **66**. The penetration region **62** comprises slits or score lines **74** that pass partially, but not completely, through from the outside. The slits **74** may also advantageously fully penetrate the main adhesive disc **64** and the hold down disc **66**. The central area around the penetration region **62** is preferably transparent or clear, to permit viewing of the incision site while the hold down disc **66** and main adhesive disc **64** are being advanced against the patient. The hold down disc **66** and the backbone structure of the main adhesive disc **64** are fabricated from materials including, but not limited to, cardboard,

polystyrene, polyvinyl chloride, polyester, polyimide, polyamide, polyethylene, polypropylene, and the like, and they may be integrally formed. While the hold down disc **66** and the main adhesive disc **64** should be semi- rigid or have reduced flexibility, the hold down straps **68** are preferably of greater flexibility. The flexibility can be achieved by weaving or knitting structures of the polymers such as polyester cloth and the like.

The adhesive region **70** is designed to be fastened to the chest tube to hold the chest tube from being dislodged from the patient. The adhesive region **70** may alternatively be fabricated using Velcro or other fastener systems that mate with corresponding systems attached to the chest tube **10**. If adhesives are used in the adhesive region **70**, a paper or plastic cover strip, removable before use, is desirable to protect the adhesive.

The main adhesive disc **64** is coated, on the patient side, with a strong skin adhesive. Such adhesives include cyanoacrylates, but preferably include aggressive adhesives that may be removed or un-adhered such as those adhesives that are used on the pads of electrocardiogram (EKG) electrodes. The adhesive may optionally comprise antigenic, antibiotic or anti-microbial agents such as, but not limited to, silver azide, silver chloride and the like. The adhesive region is, preferably, covered with a plastic or paper cover that is removed by the practitioner, prior to adhering the disc to the patient. Prior to adhesion of the hold down disc **60** to the patient, the practitioner preferably scrubs the area with betadine or other antimicrobial agent using standard aseptic technique.

Figure 5B shows the hold-down disc **60** adhered to the patient **50**. The hold down straps **68** are wrapped around and adhered to the chest tube **10**, holding the chest tube **10** in place. The cutter handle **22** and obturator handle **26** are not visible in Figure 5B because they have been removed from the chest tube **10**.

Figure 6A illustrates an incision apparatus **100**, with its cutter retracted. The incision apparatus **100** comprises a cutting blade **102**, a shaft **104**, a chest plate **106**, a bearing **108**, a housing **110**, a spring **112**, a handle **114**, a travel stop **116**, a locking mechanism **118**, and a lock extension **120**.

Referring to Figure 6A, the cutting blade **102** is permanently affixed to the distal end of the shaft **104** while the handle **114** is permanently affixed to the proximal end of the shaft **104**. The shaft **104** slideably moves through bearing **108** that is permanently affixed to the housing **110**, which is further affixed to the chest plate **106**. The spring **112** biases the shaft **104** so that the cutting blade **102** is retracted within the housing **110**. The travel stop **116** is affixed to the housing **110** and limits travel of the handle **114**. The locking mechanism **118** is affixed to either the chest plate **106** or the housing **110**. The locking mechanism is affixed to the lock extension **120**. The lock extension **120** selectably engages the cutter **102** to prevent inadvertent advancement of said cutter **102** until desired.

The cutting blade **102** is preferably fabricated from stainless steel and is configured to form a cross or X. The cutting blade **102** may also be a single blade or other

configuration. The cutting blade **102** may be pointed or rounded in side view.

The spring **112** is preferably a concentric coil spring fabricated from stainless steel, Elgiloy, nitinol or other suitable spring material. The spring **112** can also be a leaf spring or have a non-concentric configuration.

The chest plate **106**, the housing **110**, the handle **114**, the locking mechanism **118**, the lock extension **120**, and the travel stop **116** are fabricated from polymeric materials including as but not limited to PVC, polycarbonate, acrylic, Delrin, polypropylene, PEEK or other suitable rigid material. The chest plate **106** is preferably transparent and may be provided with an adhesive on the skin contacting surface **107**.

Referring to Figure 6A, the chest plate **106** is placed against the chest of the patient so that the center of the chest plate **106** is at the desired incision point. The chest plate **106** is held against the chest of the patient and the locking mechanism **118** is disengaged. Manual force is applied to the handle **114**, which advances the cutter **102** until such point as the handle **114** hits the travel stop **116**. Release of manual pressure from the handle **114** causes the spring **112** to retract the blade **102** back within the housing. The incision apparatus is designed to cut through only the skin, fascia, and fat of the patient and limit deeper advancement of the blade. The travel stop **116** prevents the blade **112** from penetrating lower than the level of the ribs, so as to avoid damage to underlying organs.

Figure 6B illustrates a side view of an incision apparatus **100** with its cutter advanced. The incision apparatus **100** comprises a cutting blade **102**, a shaft **104**, a chest plate **106**, a bearing **108**, a housing **110**, a spring **112**, a handle **114**, a travel stop **116**, a locking mechanism **118**, and a lock extension **120**. The locking mechanism **118** has been withdrawn permitting the cutting blade **102** to be forced beyond the face of the chest plate **106** and into the patient. The handle **114** is now impinging on the travel stop **116** to prevent the cutting blade **102** from being advanced too far beyond the chest plate **106** and thus injure the patient. The spring **112** is compressed to provide biasing of the cutting blade **102** away from the patient after the force on the handle **114** is removed.

Figure 6C illustrates a bottom view of an incision apparatus **100**. The cutting blade **102** is clearly shown with an "X" configuration in this embodiment. The shaft **104** and the bearing **108** are visible in this view.

Figure 7 illustrates another embodiment of the chest tube **10**. The chest tube **10** comprises a length of tubing **12**, an optional valve **13**, a plurality of distal openings or drainage ports **14**, an optional gripping or friction surface **15**, a central lumen **16**, a drainage connector **18**, an obturator **24**, an obturator handle **26**, and an obturator control rod **30**. The length of tubing **12** comprises a wall and a central lumen **16**. The openings **14** are holes extending through the tubing wall from the exterior to the central lumen **16**. The optional valve is affixed integral to or separate from the tubing **12**. The friction surface **15** is integral to the tubing **12** but may be a separate structure slidably disposed over the tubing **12**. The

drainage connector **18** is affixed to the proximal end of the tubing **12**. The obturator **24** is slidably disposed within the central lumen **16** of the tubing **12**. The obturator **24** is affixed to the distal end of the obturator control rod **30**. The obturator handle **26** is affixed to the proximal end of the obturator control rod **30** and extends outside the drainage connector **18**.

The obturator **24** could also be termed a nose cone, blunt trocar or other designation. The obturator **24** is wedge shaped but could alternatively be symmetrical in configuration. The obturator **24** is not sharp enough to cut through skin under pressures up to 20 pounds. The obturator **24** is, however, able to optionally bluntly dissect muscle and pleural tissue under forces of approximating **20** pounds. The obturator **24** is removed from the chest tube 10 by grasping the obturator handle **26** and withdrawing said obturator handle **26**, which removes the obturator **24** by withdrawing the attached obturator control rod **30**. The obturator control rod **30** possesses column strength and resistance to elongation under tension but is flexible to at least some degree. This flexibility permits the obturator control rod **30** and the chest tube **10** to bend during insertion into the patient, thus minimizing the risk of internal organ perforation. The obturator control rod **30** optionally possesses variable flexibility. It is preferred that the obturator control rod **30** is more flexible toward the distal end and less flexible toward the proximal end. Referring to Figures 1B, 1C and 7, this embodiment of the chest tube **10** may also comprise a malleable shaft **32**.

Figure 8A illustrates a packaged chest tube system **150** comprising an axially elongate cannula tube **152** with a central lumen (not shown), a plurality of distal openings **154**, an optional one-way valve **156**, an optional shutoff valve **158**, a connector **160**, an obturator further comprising a shaft **162** and a handle **164**, a trocar further comprising an axially elongate cylindrical shaft **166**, a beveled tip **168**, and a limit stop **170**, an inner pouch **172** further comprising a plurality of chevron opening regions **176**, a hold down disc **178** further comprising a protective cover sheet (not shown), a central slit region **180**, a substrate with a clear window area **182** a plurality of hold down ties **184** each further comprising a cannula grip region **186**, and a skin adherence region (not shown), and an outer pouch **188** further comprising a plurality of chevron opening areas **190**, and labeling (not shown).

Referring to Figure 8A, the cannula tube **152** is an axially elongate tube with a central through lumen having a proximal and a distal end. The distal end of the cannula tube **152** comprises a plurality of perforations, penetrations, or holes **154** that communicate between the exterior of the cannula **152** and the central lumen. The proximal end of the cannula tube **152** is permanently or removably affixed to the one-way valve **156** and further removably affixed, preferably in series, to the shutoff valve **158** as well as the connector **160**. The shaft **162** of the obturator is removably, and slidably placed through the central lumen of the cannula tube **152**. The obturator handle **164** is permanently affixed to the shaft **162** and projects out the proximal end of the cannula tube **152** and any attachments including the connector **160**. The axially elongate shaft **166** of the trocar is concentrically,

slidably, and movably placed over the cannula tube **152**. The trocar shaft **166** is sharpened and preferably beveled on its distal end **168**. The proximal end of the trocar shaft **166** is permanently affixed to the limit stop **170**, which further comprises a central through lumen and slidably moves over the cannula tube **152**.

Further referring to Figure 8A, the outer pouch **188** is preferably comprised of an upper layer and a lower layer not shown. The upper layer and the lower layer are preferably heat sealed together so as to form a complete barrier against microbial contaminants. The band where the upper layer is sealed to the lower layer is called the heat seal **214**. The outer pouch **188** preferably comprises one or more openable areas, or chevrons **190**, that are comprised by heat seals that are disposed diagonally across the corners of the outer pouch **188** to permit a user to grab the upper layer separately from the lower layer and tear the two layers apart at the chevron **190**. The outer pouch **188** further preferably comprises a label, which is either integral or adhered to the outer pouch **188**. The inner pouch **172** is fabricated using similar techniques as the outer pouch **188**. Preferably the inner pouch **172** comprises an upper and a lower layer that are heat sealed together with opening chevrons **176** and heat seals **212**. The inner pouch **172** further comprises a hold down disc **178** that is permanently affixed, removable, or integral to the distal end of the inner pouch **172**. The hold down disc **178** is fabricated from a substrate **182** that forms the main body of the hold down disc **178**. The substrate **182** is coated on the distal most side with an adhesive that is skin compatible and preferably adheres to wet skin. The substrate **182** further comprises a window area, which is a clear or

transparent region permitting visibility through the hold-down disc at least in its central region. The substrate **182** is partially, or completely perforated at its central region in, for example, a cross or "X" shape, to permit easy penetration of the hold-down disc by the distal tip of the cannula **152**. The hold-down disc **178** is preferably folded flat so as to be insertable into the outer pouch **188** with a minimum profile. The hold-down disc **178** further is permanently affixed to one or more tie down straps **184** that further are coated with adhesive near the ends to form adhesive regions **186**. The tie-down straps **184** are disposed within the interior of the inner pouch **172**. They may be separate or pre-attached to the cannula **152**. If separate, the adhesive regions **186** of the tie down straps **184** are covered by a protective peel-away layer (not shown).

The hold-down disc **178**, in another embodiment, is a flexible, elastomeric, rigid or semi-rigid piece of polymer, metal, or the like and is configured with a soft, pliable exterior edge. The hold-down disc **178**, in this embodiment, is a suction cup that adheres to the patient's skin by way of suction. A port, valve, and suction bulb for manual evacuation are optionally beneficial to this embodiment in that they can be used to enhance the vacuum bond created by the basic suction cup design.

The hold down disc **178** is, preferably, affixed to or integral to the inner pouch **172** and the proximal side of the hold down disc **178** comprises part of the interior of the inner pouch **172**. Because the inner pouch **178** is flexible, the hold-down disc **178**, which is normally in the plane orthogonal to that of the inner pouch **172** or the cannula **152**, may be turned sideways so that it resides in a

generally coplanar disposition relative to the inner pouch **178** and cannula **152** during packaging, shipping, and storage.

The trocar comprised by the shaft **166**, the limit stop **170** and the sharpened end **168** is very short. The trocar is intended to be forced into a skin incision made in the patient's chest. The trocar cannot penetrate very far because the distance between the sharpened end **168** and the distal end of the limit stop **170** is limited. In a preferred embodiment, the limit stop **170** is large in diameter and stops against the outside of the skin. The diameter of the limit stop **170** is between 1 and 20 cm, and preferably between 2 and 10 cm and more preferably between 3 and 6 cm. The length of the shaft **166** is between 1 and 10cm and preferably between 2 and 5cm. The length of the shaft **166**, in this embodiment, will need to be tailored to the individual because each person has a different amount of fat so different sizes may be required, for example, large, medium, and small. Thus, the distal segment of the cannula which enters the body may be provided in various predetermined lengths to suit patients of varying physique, and the practitioner may select a suitably short device for use after appraisal of the patient.

In another embodiment of the trocar, the limit stop is smaller in diameter and stops against the outside of the ribs. In this latter embodiment, the limit stop **170** is passed inside a skin incision and through fat layers so that it stops at or near the outer region of the ribs. The diameter of the limit stop **170** in the latter embodiment is between 1 and 5 cm and preferably between 1 and 3cm. The length of the shaft **166** is between 1 and 5cm and,

preferably between 1.5 and 4cm so that it passes through the ribs and into the pleural space but does not project far into the pleural space. This embodiment avoids much of the issues with regard to amount of body fat on a person and allows for a one-size-fits-all approach, so that the distal segment of the cannula may be provided in a single predetermined length suitable for safe, stop-limited penetration through the rib cage.

Figure 8B illustrates a packaged chest tube system **200** comprising an axially elongate cannula **152** with a central lumen (not shown), a plurality of distal openings **154**, an optional one-way valve **156**, an optional shutoff valve **158**, a connector **160**, a trocar further comprising an axially elongate cylindrical shaft **166**, a beveled tip **168**, and a limit stop **170**, an inner pouch **202** further comprising an upper layer and a lower layer (not shown), a plurality of heat seals **212**, a drainage volume **204**, a drainage inlet manifold **206**, an optional vacuum port **208**, an optional stopcock **210**, an optional vacuum pump (not shown), a hold down disc **178** further comprising a protective cover sheet (not shown), a central slit region **180**, a plurality of hold down ties **184**, a substrate with a clear window area **182**, and a skin adherence region (not shown), and an outer pouch **188**, further comprising an upper layer and a lower layer (not shown), a plurality of heat seals **214**, a plurality of chevron opening areas **190**, and labeling (not shown).

The embodiment of Figure 8B is similar to that of Figure 8A, except that the inner pouch **202** comprises the drainage volume **204**, the drainage inlet manifold **206**, the optional vacuum port **208**, the optional stopcock **210**, and the optional vacuum pump. These components are either

integral to the inner pouch **202** or are affixed and bonded to the inner pouch **202** using heat, solvents, adhesives, ultrasonic welding, or the like. Referring to Figure 8A, the cannula **152** of Figure 8B does not comprise an obturator shaft **162** or handle **164**, although these could be added, if desired. In this embodiment, the extreme distal tip of the cannula **152** is advantageously of increased stiffness, or has decreased flexibility, relative to the rest of the shaft **152**. In this way, by careful location of the distal tip of the cannula **152** relative to the trocar shaft **166** and sharpened end **168**, the cannula **152** serves the function of the blunt obturator.

Referring to Figure 8B, the drainage volume **204** serves as an integral collection device, much like a pleur-evac. The drainage volume **204** is connected to the connector **160** of the cannula **152** by way of the drainage manifold **206**. The drainage volume may comprise an optional standoff to maintain a finite internal volume for maintenance of a pre-applied or generally applied vacuum. The vacuum pump may be a simple manual bulb or it may be any of the typical manual or electromechanical devices available.

Further referring to Figures 8A and 8B, the method allows for placement of a chest cannula **152** in a patient without the need to use gloves since the cannula **152** and any associated apparatus is handled through the protective pouches or bags. The entire system is sterilized. The chest tube **152** and its components, and the inner pouch **202**, both inside and outside, are maintained sterile by the outer pouch **188**. The patient incision site is first swabbed with iodine, betadine, or other disinfectant. An incision is made, with a sharp blade, through the skin and

into the fat layers. After removal of the outer pouch **188**, the chest tube or cannula **152** may be manipulated through the inner pouch **202**. The hold down disc **178** is adhered to the skin at the incision site. The trocar and concentrically mounted chest tube **152** are forced through the central slits **180** in the hold-down disc **178** and into the incision. The trocar is forced into the incision until the limit stop **170** hits the hold down disc **178**. The trocar is withdrawn and the chest tube cannula **152** is advanced into the incision. Once placement is acceptable, the tie down straps **186** are wrapped around the cannula shaft **152** and chest drainage management can commence.

Figure 9A illustrates an expandable trocar **250** comprising a limit stop **252**, a plurality of split sleeves **254**, an obturator stop **256**, an obturator handle **258**, and an obturator shaft **260**.

Referring to Figure 9A, the plurality of split sleeves **254** are disposed concentrically at their minimum potential diameter. The split sleeves **254** are embedded in or affixed to elastomeric or malleable material that is affixed to a central lumen of the limit stop **252**. The obturator shaft **260** is preferably rounded at its distal end and is affixed to the obturator stop **256**, which is further affixed to the obturator handle **258**. The obturator shaft **260** is movably, removably, and slidably disposed within the central lumen described by the split sleeves **254**. The rounded distal end of the obturator shaft **260** is positioned so that when the obturator stop **256** is against the proximal side of the limit stop **252**, the rounded section fully projects beyond the distal end of the split sleeves **254**.

The number of split sleeves **254** is between 2 and 100, and preferably between 4 and 50, and more preferably between 6 and 20.

The region between the split sleeves **254** is either open or it is filled in with an elastomeric material such as, but not limited to polyurethane, silicone elastomer, thermoplastic elastomer, latex rubber, polyethylene foam, polyvinyl chloride foam, polyurethane foam, and the like.

Figure 9B illustrates a bottom view of the expandable trocar shown in Figure 9A, further comprising the obturator shaft **260**, the plurality of split sleeves **254**, the limit stop **252**, and the expandable region **262**.

Referring to Figures 9A and 9B, the limit stop **252** as well as all components of the obturator are preferably fabricated from metals such as, but not limited to, stainless steel, cobalt nickel alloys, nitinol, or titanium, or polymeric materials such as, but not limited to, polyethylene, polypropylene, polycarbonate, polyester, polyvinyl chloride, ABS, and the like. The elastomeric or malleable material, in which the split sleeves **254** are embedded, is preferably a material such as, but not limited to polyurethane, silicone elastomer, thermoplastic elastomer, latex rubber, polyethylene foam, polyvinyl chloride foam, polyurethane foam, and the like. The split sleeves **254** are fabricated from materials such as, but not limited to, stainless steel, cobalt nickel alloys, nitinol, or titanium, and the like. The elastomeric region in the limit stop **252** embeds the split sleeves **254** and allows them to expand under the force of a tapered obturator or central insertable mass. In another embodiment, the elastomeric region **262** is replaced by cantilevered split sleeves **254**

that are embedded into the limit stop **252**. The split sleeves **254** are leaf springs and expand in the presence of a large insertable central mass.

Figure 9C illustrates the expandable trocar **250** of Figure 9A with the obturator components **260**, **256**, and **258** removed and a large expanding obturator **270** being inserted. The large expanding obturator **270** further comprises a tapered region **272**, a blunt rounded tip (not shown), a straight shaft **274**, and an expanding obturator handle **276**. The expanding obturator **270** has not been inserted far enough to cause any expansion of the split sleeves **254**.

Figure 9D illustrates the expandable trocar **250** with the large expanding obturator **270** having been fully inserted therein. The split sleeves **254** have opened up forming a series of fingers that are intended to pry open or expand tissue. The blunt tip **278** of the expanding obturator **270** is visible in this view. It is preferable that the blunt tip **278** not project beyond the distal ends of the split sleeves **254** but a small amount of projection, as shown, is acceptable.

Figure 9E illustrates a bottom view of the expandable trocar **250** with the large expanding obturator **270** having been fully inserted therein. The elastomeric or malleable region **262** has become much narrower than in the unexpanded state of Figure 9B, due to the expansion of the embedded split sleeves **254**.

Referring to Figures 9A through 9E, the expandable trocar permits placement of a small diameter trocar through the thoracic wall, a procedure which is fairly commonplace and easy. However, by removal of the small obturator and

full insertion of the large expanding obturator **270**, the trocar **250** and the hole in the tissue it supports is expanded greatly and in such a way that a chest tube could be inserted therethrough. In yet another embodiment of the expandable trocar **250**, the obturator shaft **260** is sharpened and capable of cutting through the skin, fat, fascia, and muscle of the patient. The sharp tip on the obturator shaft **260**, in this embodiment would be retracted automatically by standoffs that projected distally of the limit stop **252** and were attached to the obturator stop **256** or obturator handle **258**. Automatic retraction of the sharp tip of the obturator shaft **260** would permit a one-step procedure or method to punch a hole in the thoracic wall and insert the trocar **250** through the ribs to the limit stop **252** without the need of a scalpel or other sharp object to make the initial skin incision.

Figure 10A illustrates a short chest tube **300** comprising a cannula tube **302**, a plurality of drainage holes **314**, a limit stop **304**, a tube standoff **306**, a one-way valve **308**, a stopcock **310**, and a drainage connector **312**. The short chest tube **300** is shown inserted through an incision through a skin **320**, a fat layer **322**, a layer of fascia **330**, a region of intercostal muscle **324**, between the ribs **326**, through the pleura **328**, and into the pleural space **332**.

Referring to Figure 10A, the cannula tube **302** is an axially elongate hollow tube with a proximal and a distal end. The proximal end of the cannula tube **302** is affixed to the limit stop **304**, which is affixed to the tube standoff **306**, which is affixed to the one-way valve **308**, which is affixed to the stopcock **310**, which is affixed to

the distal end of the drainage connector **312**. A central through lumen is maintained from the distal end of the cannula tube **302** to the proximal end of the drainage connector **312** so that fluid can be drained from the thoracic cavity. The one-way valve **308** prevents backflow into the thoracic cavity but opens to provide a through lumen for drainage. The stopcock **310** provides manual shutoff or opening of the through lumen. The drainage holes **314** communicate between the through lumen and the outside of the cannula tube **302**. The plurality of drainage holes **314** are provided since a single hole, at the distal tip for example, might become occluded with tissue and drainage could not occur. The plurality of holes **314** separated by the material of the cannula tube **302** provides a standoff for the tissue and maximizes the surface area for drainage of the pleural space.

Referring to Figure 10A, the short chest tube **300** may be forced between the ribs **326** and into the pleural space **332** with reduced risk of damage to internal organs since the distal end of the cannula tube **302** is rounded and blunt. In addition, the length of the cannula tube **302** is short so that it projects just a small amount into the pleural space **332**. The cannula tube **302** is provided, for example in several lengths to accommodate people with different thicknesses of body fat. The diameter of the cannula tube **302** is between 0.25cm and 4cm and preferably between 0.5cm and 2 cm. The limit stop **304** prohibits the short chest tube **300** from being advanced too far into the patient and, thus, minimizes the risk of damage to the underlying organs such as the heart and lungs. The lengths and diameters of the limit stop **304** and the construction

materials is the same as that described for the trocar **250** shown in Figures 9A through 9E.

Figure 10B illustrates a short deflecting trocar and chest tube system **350** where the trocar comprises a trocar tube **352**, a deflecting tip **354**, a limit stop **356**, and a sealing handle **358**. The chest tube comprises a cannula **360**, a plurality of drainage holes **362**, an optional obturator shaft **364** and an optional obturator handle **366**, a one-way valve **368**, a stopcock **370**, and a drainage connector **372**. The short deflecting trocar and chest tube system **350** is shown inserted through an incision through a skin **320**, a fat layer **322**, a layer of fascia **330**, a region of intercostal muscle **324**, between the ribs **326**, through the pleura **328**, and into the pleural space **332**.

Referring to Figure 10B, the short deflecting trocar and chest tube system **350** permits placement of a short trocar through the ribs and into the pleural space. A chest tube cannula **360** is then inserted therethrough and deflected so that it can route parallel to the plane of the chest wall to a desired location. The obturator shaft **364** and the obturator handle **366** are preferably omitted from the system but may advantageously be added if additional column strength or steerability is desired.

The trocar sealing handle **358** is fabricated from rigid polymers such as, but not limited to ABS, PVC, polyethylene, polypropylene, polysulfone, polycarbonate, and the like, and further comprises a central lumen with an elastomeric seal through which the cannula shaft **360** may slidably and movably pass but which seals and prevents the passage of air or liquid around said cannula shaft **360**. The elastomeric seal (not shown) is fabricated from

materials such as, but not limited to, silicone elastomer, latex rubber, thermoplastic elastomer, polyurethane, and various closed-cell or open-cell foams. The inner surface of the elastomeric seal is advantageously coated with a lubricant such as silicone oil, or the like, to facilitate movement of the cannula shaft **360** through the sealing handle **358**.

Referring to Figure 10C, the limit stop **304** is sized and dimensioned to permit advancement through the fat layer **322** overlying the patient's rib cage, but prevent advancement into the narrow space between the ribs **326**. In this arrangement, the length of the tube **302** distal to the stop is set at a predetermined length corresponding to the average thickness of the ribs, so that the distal tip of the tube extends into the pleural space **332** without significant risk of injuring tissue therein. In all other respects, the chest tube may be similar to the chest tubes of the previous figures.

The advantage of the aforementioned devices and methods improves the ease with which a chest tube may be placed, especially by less well-trained personnel such as paramedics and emergency medical technicians.

Application of the chest tube system provides improved speed of application of the chest tube, especially in contaminated environments. The application of this chest tube system facilitates damage control procedures wherein the patient can be allowed to stabilize prior to definitive repair of the injuries. The aseptic hold-down disc and the incision apparatus allow for quicker application of the chest tube by paramedics and emergency personnel with less

chance of wound contamination, internal damage to the patient or chest tube dislodgement.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. For example, the aseptic hold down disk may have more than two straps to restrain the chest tube. The incision apparatus may have a cocking mechanism to retract and then fire the cutter, rather than using positive hand pressure to advance the cutter. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is therefore indicated by the appended claims rather than the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.